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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,049	01/17/2006	Jingyu Liang	2108.0060000/MAC	5056
26111 7590 09/23/2008 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005				
EXAMINER KEYS, ROSALYND ANN				
ART UNIT		PAPER NUMBER		
1621				
MAIL DATE		DELIVERY MODE		
09/23/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/531,049

Applicant(s)

LIANG ET AL.

Examiner

ROSALYND KEYS

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2008 and 12 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,6,8 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,6,8 and 11-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 2, 3, 6, 8, and 11-15 are pending.

Claims 2, 3, 6, 8, and 11-15 are rejected.

Claims 1, 4, 5, 7, 9 and 10 have been cancelled.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 12, 2008 has been entered.

Response to Amendment

Claim Objections

3. The objection to Claim 11 is withdrawn due to the amendment to claim 11, filed August 14, 2008, which adds a period at the end of the claim.

Claim Rejections - 35 USC § 112

4. The rejection of Claims 11-15 under 35 U.S.C. 112, first paragraph, is withdrawn due to the amendment to claim 11, filed August 14, 2008, which incorporates the diseases disclosed on in the first paragraph on page 4 of the specification.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 2, 3, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dittrich et al. (Phytochemistry, Vol. 11, 1971, pp. 245-250) in view of Sultana et al.

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(Phytochemistry, Vol. 50, 1999, pp. 1249-1253) or Page et al. (US 6,002,025) and Liu (US 5,969,165).

Dittrich et al. teach that the compound 5-O-methyl-myo-inositol (sequoyitol) is found in the Taxaceae class and family of plants, but Dittrich et al. do not disclose a method of extracting said compound from said plants.

The steps and solvents disclosed in claims 2, 3, 6, and 8 are well known and are taught for example by Sultana et al. (see section 3.2 on pages 1251 and 1252), Page et al. (see column 7, line 48 to column 9, line 2) and Liu (see column 1, line 18 to column 6, line 43). Liu additionally teaches the use of a macroporous resin (see example 1, in particular column 5, lines 62-66). Liu further teaches that his method allows for large industrial scale production (see column 1, lines 41-57).

One having ordinary skill in the art at the time the invention was made would have found it obvious to extract the compound 5-O-methyl-myo-inositol (sequoyitol) from the Taxaceae class and family of plants as disclosed in Dittrich et al. by using well known steps and solvents such as those taught by Sultana et al., Page et al. and Liu

Sultana et al. and Page et al. do not disclose that their columns are macroporous. However, Liu, which teaches similar isolation and purification steps as Sultana et al. and Page et al. teach the use of a macroporous resin and further teaches that his process allows the isolation to be conducted via a large industrial scale production. One having ordinary skill in the art at the time the invention was made would have found it obvious to utilize a column having the pore size necessary for obtaining the desired separation based upon the scale of production desired. The

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claims would have been further obvious because "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." KSR International Co. v. Teleflex Inc., 550 U.S.____, 82 USPQ2d 1385, 1395-97 (2007).

Further, where the process steps of Sultana et al., Page et al. (US 6,002,025) and Liu differ from the instant claims in the order in which the steps are performed the instant claims are still considered to be prima facie obvious because the time at which a particular step is performed is simply a matter of operator preference, especially since the same result is obtained regardless of when the step occurs. See Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render prima facie obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.)

9. Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostlund et al. (US 5,550,166) in view of Dittrich et al. (Phytochemistry, Vol. 11, 1971, pp. 245-250) and Oberley Free Radic Biol Med. 1988;5(2):113-24 (abstract) [online],

[retrieved 2008-05-11]. Retrieved from the internet <URL:

<http://www.ncbi.nlm.nih.gov/pubmed/3075947>.

Ostlund et al. teach the compound pinitol, compositions containing pinitol and its use in the treatment of diabetes (see entire disclosure, in particular column 1, lines 12 to 30 and column 3, line 11 to column 5, line 52). Pinitol is a stereoisomer of the claimed sequoyitol (see page 246 of Dittrich et al.). One having ordinary skill in the art at the time the invention was made would have found it obvious to utilize 5-O-methyl-myoinositol (sequoyitol) in a composition for the treatment of diabetes, as taught by Ostlund, because compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). See also *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (stereoisomers prima facie obvious).

Ostlund et al. in view of Dittrich et al. do not teach the improvement in the metabolism of free radicals.

Oberley teaches that not only are oxygen radicals involved in the cause of diabetes, they also appear to play a role in some of the complications seen in long-term treatment of diabetes.

One having ordinary skill in the art at the time the invention was made would reasonably expect that based upon the teachings of Oberley, that treatment of diabetes and its complications in the manner taught by Ostlund et al. in view of Dittrich et al.

would also involve treatment of free radicals which according to Oberley is a cause of diabetes.

Response to Arguments

10. Applicant's arguments filed August 14, 2008 have been fully considered but they are not persuasive.

The first rejection under 35 U.S.C § 103

The Applicants submit that the procedures of sequoyitol's isolation that are described in the prior art were not optimized for large scale production. Rather they were performed only in much smaller scales for laboratory assays.

This submission is not persuasive because Liu teaches an isolation and purification method, which is similar to the methods of Sultana and Page, which is done in a large scale production. Thus, adaptation of the isolation and purification methods of Sultana and Page to a large scale production process is within the capabilities of one having ordinary skill in the art, as taught by Liu.

Thus, the Examiner believes that claims 2, 3, 6, and 8 are prima facie obvious.

The second rejection under 35 U.S.C § 103

The Applicants arguments with regard to Ostlund and Dittrich is not persuasive because the skilled artisan would expect sequoyitol and D-pinitol to have similar properties because unlike the azole nucleoside of D-pinitol and myo-inositol, sequoyitol and D-pinitol have the same functional groups on the same position of the ring. Compounds which are position isomers (compounds having the same radicals in

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physically different positions on the same nucleus) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). See also *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (stereoisomers *prima facie* obvious).

The Examiner believes that Ostlund, Dittrich and Oberley render claims 11-15 *prima facie* obvious.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROSALYND KEYS whose telephone number is (571)272-0639. The examiner can normally be reached on M, W, F 8 am-3:30 pm; T, Th 5:30 am-7 am & 9:30 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ROSALYND KEYS/
Primary Examiner, Art Unit 1621

September 19, 2008